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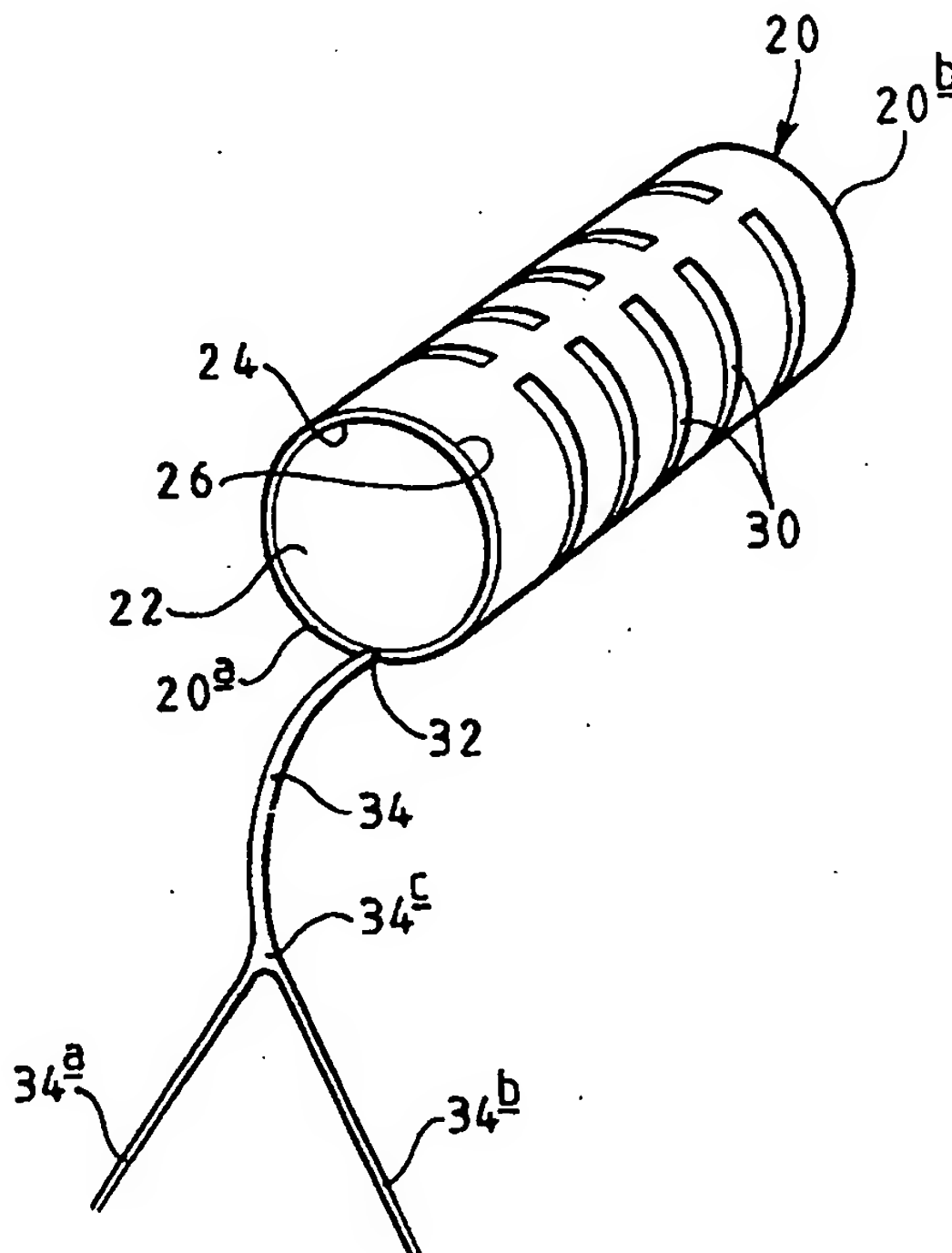
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/06, A61B 17/12		A1	(11) International Publication Number: WO 99/00073 (43) International Publication Date: 7 January 1999 (07.01.99)
(21) International Application Number: PCT/GB98/01850 (22) International Filing Date: 24 June 1998 (24.06.98) (30) Priority Data: 9713624.6 28 June 1997 (28.06.97) GB (71) Applicant (for all designated States except US): ANSON MEDICAL LIMITED [GB/GB]; The Innovation Centre, 68 Milton Mark, Abingdon, Oxford OX14 4RX (GB). (72) Inventor; and (75) Inventor/Applicant (for US only): ANSON, Anthony, Walter [GB/GB]; 101 Martindale Road, Hounslow, Middlesex TW4 7EZ (GB). (74) Agents: PEARCE, Anthony, Richmond et al.; Marks & Clerk, Alpha Tower, Suffolk Street Queensway, Birmingham B1 1TT (GB).			(81) Designated States: AU, BR, IL, JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: EXPANDABLE DEVICE

(57) Abstract

An expandable device, e.g. a stent for insertion into a passage, e.g. a blood vessel or artery, is disclosed. The device has a body (20) formed of a flexible material. The body is convertible from a collapsed condition in which it is of a size to be inserted into the passage into an expanded condition in which the body (20) is fixed relative to the passage. A passage (28) is provided within the body so as to extend over at least a region of the latter. An inlet (32) is provided in the body (20) in communication with the passage therein. The inlet (32) enables a rigidifying material to be introduced into the passage (28) in the body (20) so that at least the region of the body (20) in which the passage is provided can be rigidified whereby to maintain the body in its expanded condition.



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EXPANDABLE DEVICE

This invention relates to an expandable device for insertion into a passage for the purpose of dilating the passage and/or maintaining it open, or occluding the passage and is more particularly concerned with an expandable device for use in medical applications where it can be used to dilate or maintain the luminal patency of arteries and other vessels which may have become partially or completely blocked, or to occlude undesired passages or openings such as between certain arteries or between heart chambers.

The use of expandable devices for insertion into a passage is particularly widespread in the medical field, where such devices are generally referred to as stents. Such stents are generally constructed of metal wire which may be braided (EP-A-0183372), wound (WO/9315661) or knitted (WO94/12136), or alternatively from tubing having perforated walls (WO95/03010).

Current stents are either balloon expanding or self expanding. Balloon expanding stents are the most common and rely on a balloon temporarily placed within the previously compacted stent to distend the stent radially and so lodge the stent firmly against the wall of the vessel within which it is located. However, problems can arise if there is any elastic recoil (i.e. radial contraction) of the stent once the balloon is removed.

Self expanding stents are made from a more elastic material which is constrained to a small diameter for insertion but which will expand to a larger diameter when deconstrained, without the need for any expanding means. Self-expanding stents made of shape-memory material are also

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known (see for example EP-A-066065). A medical practitioner must be careful in selecting an appropriate stent for each procedure, since situations may arise in which the outward pressure of the stent on the vessel is too great, causing physiological damage, or too small, resulting in dislodgement of the stent.

It is an object of the present invention to provide an expandable device which can be fixed in its expanded condition in a passage, so as to minimise movement of the expanded device in the passage.

According to a first aspect of the present invention, there is provided an expandable device for insertion into a passage, said expandable device comprising a body formed of at least one flexible material, said body being convertible from a collapsed condition in which it is of a size to be inserted into the passage into an expanded condition in which the body is fixed relative to the passage, passage means in said body and extending over at least a region of the body, and inlet means communicating with said passage means to enable a rigidifying material to be introduced into said passage means so that, in use, at least said region of said body can be rigidified whereby to maintain the body in its expanded condition.

Preferably, the body is formed of at least one flexible sheet material. Said at least one flexible sheet material may be elastomeric or non-elastomeric.

In cases where the body is formed of two or more flexible sheet materials, each may be elastomeric or non-elastomeric. Said at least one flexible sheet material may be tubular or include a tubular region.

Advantageously, the body in the collapsed condition occupies substantially the same volume as the at least one sheet material.

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Preferably, the inlet means is closable. Closure may be achieved by, for example, providing the inlet means with a heat-sealable closure, or alternatively the inlet means may be a self-sealing valve.

The device may also include filler means, such as an elongate tube, said filler means communicating with said passage means in the body via the inlet means. The filler means may be used to expand the body of the device and/or introduce the rigidifying material into the body through the inlet means. Preferably, the filler means is separable from the remainder of the device.

According to a second aspect of the present invention, there is provided an expandable device according to said first aspect of the present invention in combination with a rigidifying material for introduction into said passage means through said inlet means.

According to a third aspect of the present invention, there is provided a method of positioning an expandable device according to said first aspect in a passage, comprising the steps of:

- (a) introducing into the passage an expandable device according to said first aspect of the present invention with the body being in a collapsed condition;
- (b) converting the body into an expanded condition so that it is fixed relative to a sidewall of the passage; and
- (c) causing the flowability of rigidifying material introduced into the passage means to be decreased so as to maintain the body in its expanded condition.

Such positioning may be effected to (i) dilate or (ii) occlude the passage, or (iii) maintain the passage at an existing dilation. Additionally, such

positioning may be effected to prevent ingress of material into the passage (eg. growths such as tumours in medical applications) and/or egress of material out of the passage, for example, if the passage is damaged (eg. aneurysm).

The body of the device may be inserted so as to be wholly within the passage, in which case fixing of the body relative to the passage is achieved by engagement of a sidewall of the body with the sidewall of the passage.

Alternatively, the body of the device may be inserted so as to be partially located within the passage, in which case said fixing may be achieved by expansion of at least one end of the body located externally of the passage, as an alternative to or in addition to the method of fixing described in the immediately preceding paragraph. Preferably, said fixing is achieved by expansion of opposite ends of the body externally of respective opposite ends of the passage, particularly where said passage is an opening such as between certain arteries or between heart chambers.

The rigidifying material may be a chemically reactive liquid or other fluid which can be caused to solidify, gel or otherwise set or experience an increase in its viscosity when in the passage means in the body. For example, the flowable rigidifying material may be selected from a flowable polymerisable monomer or monomer mixture or a flowable pre-polymer, such as an epoxy resin, a silicone elastomer, a cyanoacrylate or methacrylate.

The rigidifying material itself may be used to effect step (b) above by introducing it under pressure into the passage means in the body.

However, a hydraulic or pneumatic pressurising medium may be used for

this purpose in addition to or instead of the rigidifying material.

Additionally or alternatively, a balloon catheter may be used to move the body into its expanded condition.

In one embodiment, the sidewall of the body which engages with the sidewall of the passage in use, is formed of at least one flexible sheet material. The passage means may be disposed inwardly or outwardly of said at least one flexible sheet material or between the flexible sheet materials when more than one is provided. The passage means may be defined at least partly by said at least one sheet material. The passage means may be defined by one or a series of channels extending over at least one surface of said at least one sheet material. When a series of channels is provided, said channels need not be in communication, in which case more than one inlet and filler means may be provided.

Examples of suitable flexible materials for the body include polyesters and polyurethanes. The flexible material may be chemically coated. In particular, the sidewall which engages against the sidewall of the passage may be coated. For example, in medical applications, the sidewall may be coated with cytotoxic agents to treat tumours and/or to discourage tumour growth into the passage. Alternatively, or in addition, a coating of a relatively inert nature may be used to prevent or limit adverse biological reactions between the passage and the body. Examples of such coatings may comprise diamond-like carbon, a ceramic or metals (eg. gold, silver, platinum).

The channel or channels may be defined by two superimposed sheet materials which are sealed together at selected regions so that unsealed regions of the sheet materials define wall of the channel or channels. Alternatively, the channel or channels may be defined on a surface of the

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sheet material by sealing longitudinal side edges of a suitably shaped strip or strips of flexible material to said surface.

Two or more bodies may be connected in series. Each of the bodies may be provided with its own inlet and filler means so that, in use, each body may be expanded and/or rigidified to a different degree.

Embodiments of the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:-

Fig. 1 is a view of a first embodiment of a device according to the first aspect of the present invention,

Figs 2 to 4 show a second embodiment of a device according to the first aspect of the present invention in an expanded condition,

Figs 5 to 7 show schematically how bodies of devices according to the present invention may be collapsed,

Figs 8 and 9 show the device of Figs 2 to 4 in a collapsed condition.

Fig 10 is a view of a third embodiment of a device according to the first aspect of the present invention in an expanded condition,

Fig 11 shows the device of Fig 10 in use,

Fig 12 is a view of a fourth embodiment of a device according to the first aspect of the present invention in an expanded condition, and

Figs 13 and 14 show schematically the use of the device of Fig 12 as a patent ductus arteriosus occluder.

Referring to Fig 1, a body 2 of an expandable device comprises two superimposed flexible sheet materials which are sealed together at selected regions 4 so that unsealed regions 6 of the sheet materials define walls of channels therebetween. The sheet materials are polymeric (eg. a polyester or polyurethane) and are sealed by, for example, radio-frequency welding, ultrasonic welding or electrical resistance heating or by moulding

or casting processes.

A main channel 8 extends from an inlet 10 at a proximal edge of the superimposed sheet materials towards a distal edge thereof, with subsidiary channels 12 extending at intervals transversely of the main channel 8 and in communication therewith. A filler tube 14 is attached to the body 2 at the inlet 10 and is in communication with the channels 8, 12. The body 2 is shown in an expanded condition.

In use, the device is inserted into a passage (eg. blood vessel) with the body 2 in a collapsed condition (described more fully hereinafter) and a liquid gelling agent is passed through the filler tube 14 into the channels 8, 12 of the body 2 so expanding the body 2. In the passage, the body 2 will not be flat as shown in Fig 1, but will bend so as to adopt the shape of a sidewall of the passage. When the gelling agent sets, the body 2 will be maintained in that shape. The body 2 is then sealed at the inlet 10 and the filler tube 14 separated from the body 2 and removed from the passage.

In an alternative embodiment (not shown), the subsidiary channels 12 are slanted so as to form a series of parallel V-shapes intersecting at the main channel 8 (i.e. herringbone pattern). In other embodiments (not shown), the subsidiary channels are arranged to produce a specific expansion geometry in, for example, particular parts of the anatomy. Specifically, in a bifurcated tubular graft (eg. for the interconnection of vascular components such as the femoral arteries to the iliac arteries or in the case of abdominal aortic aneurysms where the aorta must be internally bypassed using the graft to make connections to the iliac arteries and exclude an aneurysmal sac existing at the lower end of the aorta), insertion is achieved with one branch retracted in another. The channels are arranged to ensure that on expansion, the retracted branch is retrieved from the

other branch.

Referring to Figs 2, 3 and 4, the body 20 of the device is tubular and in the expanded condition shown has a passage 22 therethrough. An inner sheet material 24 is sealed to an outer sheet material 26 at the proximal and distal ends 20a, 20b, respectively, of the tubular body 20, so as to form a single channel 28 therebetween extending over the whole of the area of the body. The outer sheet material 26 has a number of regions which form part-circumferential ridges 30 when the body 20 is in an expanded condition. An inlet 32 to the channel 28 is provided at the proximal end 20a of the body 20, said inlet 32 being connected to a filler tube 34, which divides into two tubes 34a, 34b at a branch point 34c.

In use, the device in its collapsed condition is inserted into a passage (not shown) and positioned as desired. A different component of a two-component reactive liquid is then fed into each of the two tubes 34a, 34b so that the two components combine to form a gelling mixture in the filler tube 34 which is then forced into the channel 28. The body 20 of the device becomes expanded, with the ridges 30 being formed at the same time, and subsequently rigidified. The passage is maintained open by virtue of the passage 22 through the body 20. The ridges 30 on the outer sheet material 26 help maintain the body 20 in position in the passage. Alternatively, the body may be expanded by pneumatic means such as balloon catheter (not shown). In this case, the deflated balloon catheter is placed in the passage 22 through the body 20 before the device is placed in the passage. The body 20 is then expanded by inflation of the balloon catheter before the rigidifying material is introduced into the channel 28. When the body 20 is sufficiently rigid, the balloon catheter is deflated and can be withdrawn.

Referring to Figs 5 to 7, the body 2, 20 of the device is capable of occupying a very small volume in its collapsed state relative to its volume in its expanded state. A non-tubular body 2 (eg. that exemplified in Fig 1) may be corrugated so as to form compacted pleats (Fig 5) or rolled so as to form a spiral (Fig 6). Tubular bodies 20 (eg. that exemplified in Fig 2) can be longitudinally creased and radially compacted (Fig 7). The body 2, 20 may also be formed into a helix (not shown) by constraining the proximal end and rotating the distal end.

The embodiments described above are particularly suitable for medical applications such as aneurysm repair, improving the luminal patency of an occluded vessel and preventing intimal hyperplasia (or occlusive tumorous growth in non-vascular vessels). A comparison of Figs 7 and 8 with Figs 2 and 3 illustrates the large difference in volume between the expanded and collapsed states. The small volume of the collapsed body 20 (Figs 7 and 8) allows it to be introduced into, for example, the vascular system in a catheter, with minimal invasive surgery.

Referring to Fig 10, similar parts to those in the second embodiment (Figs 2 to 4) are accorded the same reference numerals. The body 20 of the device has a tubular region 40 integrally formed with an outwardly extending annular flange 42 at the proximal 20a and distal 20b ends of the tubular region 40. The inner flexible sheet material 24 is sealed to the outer flexible sheet material 26 in strips 44 at intervals around the body 20, said sealed strips 44 extending longitudinally over the length of the tubular region 40 of body 20 and radially over an inner part of the flanges 42. As a result, a series of longitudinal channels 46 between the inner 24 and outer 26 sheet materials are interconnected on the flanges 42. The channels 46 are in communication with the inlet 32 and filler tube 34.

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Fig 11 shows the device of Fig 10 in use to interconnect two vessels 48 through tissue 49 so as to allow flow between the vessels. Depending on the degree of defect, there may be an occluded passage between the vessels 48 or no passage at all. It may be necessary to make an opening in one or both vessels to enable correct positioning of the device. In the expanded condition shown, each of the annular flanges 42 engages with a sidewall 48a of a different one of the vessels 48 so as to fix the device in position relative to the vessels 48.

Referring to Fig 12, the inner flexible sheet material 24 is sealed so as to form an enclosed volume 50. A vent 51 allows the body of the device to be collapsed. The outer flexible sheet material 26 is connected to the inner sheet material 24 by a series of ribs 52, so that a single channel 54 is formed between the sheet materials 24, 26, said channel 54 being in communication with the inlet 56 and filler tube 58. Both flexible sheet materials are non-elastomeric. On filling with rigidifying material, the body 59 adopts a diabolo shape (as shown in Fig 12).

In Fig 13, a patent ductus arteriosus 60 is shown between an aorta 62 and a pulmonary artery 64, in a condition known as patent ductus. In order to occlude the patent ductus arteriosus 60, the device of Fig 12 is passed through the patent ductus arteriosus 60 from the arterial side or the venous side of the vascular system, both techniques being commonly used. In order to facilitate passage through the ductus, the body 59 is collapsed during insertion. When the body 59 is expanded, it is engaged with a sidewall of both the aorta 62 and pulmonary artery 64 (see Fig 14). Introduction of the rigidifying material maintains the body 59 in position.

CLAIMS

1. An expandable device for insertion into a passage, said expandable device comprising a body formed of at least one flexible material, said body being convertible from a collapsed condition in which it is of a size to be inserted into the passage into an expanded condition in which the body is fixed relative to the passage, passage means in said body and extending over at least a region of the body, and inlet means communicating with said passage means to enable a rigidifying material to be introduced into said passage means so that, in use, at least said region of said body can be rigidified whereby to maintain the body in its expanded condition.
2. A device as claimed in claim 1, wherein the body is formed of at least one flexible sheet material.
3. A device as claimed in claim 2, wherein said at least one flexible sheet material is tubular or includes a tubular region.
4. A device as claimed in any preceding claim, wherein the inlet means is closable.
5. A device as claimed in any preceding claim, which also includes filler means communicating with said passage means in the body via the inlet means.
6. A device as claimed in any preceding claim, wherein the sidewall of the body which engages with the sidewall of the passage in use, is formed of at least one flexible sheet material.

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7. A device as claimed in any preceding claim, wherein the passage means is disposed inwardly or outwardly of said at least one flexible sheet material or between the flexible sheet materials when more than one is provided.
8. A device as claimed in any preceding claim in combination with a rigidifying material for introduction into said passage means through said inlet means.
9. A method of positioning an expandable device in a passage, comprising the steps of:
 - (a) introducing into the passage an expandable device as claimed in any preceding claim with the body being in a collapsed condition;
 - (b) converting the body into an expanded condition so that it is fixed relative to a sidewall of the passage; and
 - (c) causing the flowability of rigidifying material introduced into the passage means to be decreased so as to maintain the body in its expanded condition.
10. A method as claimed in claim 9, wherein the body of the device is inserted so as to be wholly within the passage, and fixing of the body relative to the passage is achieved by engagement of a sidewall of the body with the sidewall of the passage.
11. A method as claimed in claim 9, wherein the body of the device is inserted so as to be partially located within the passage, and said fixing is achieved by expansion of at least one end of the body located externally of the passage.
12. A method as claimed in claim 9, wherein said fixing is achieved

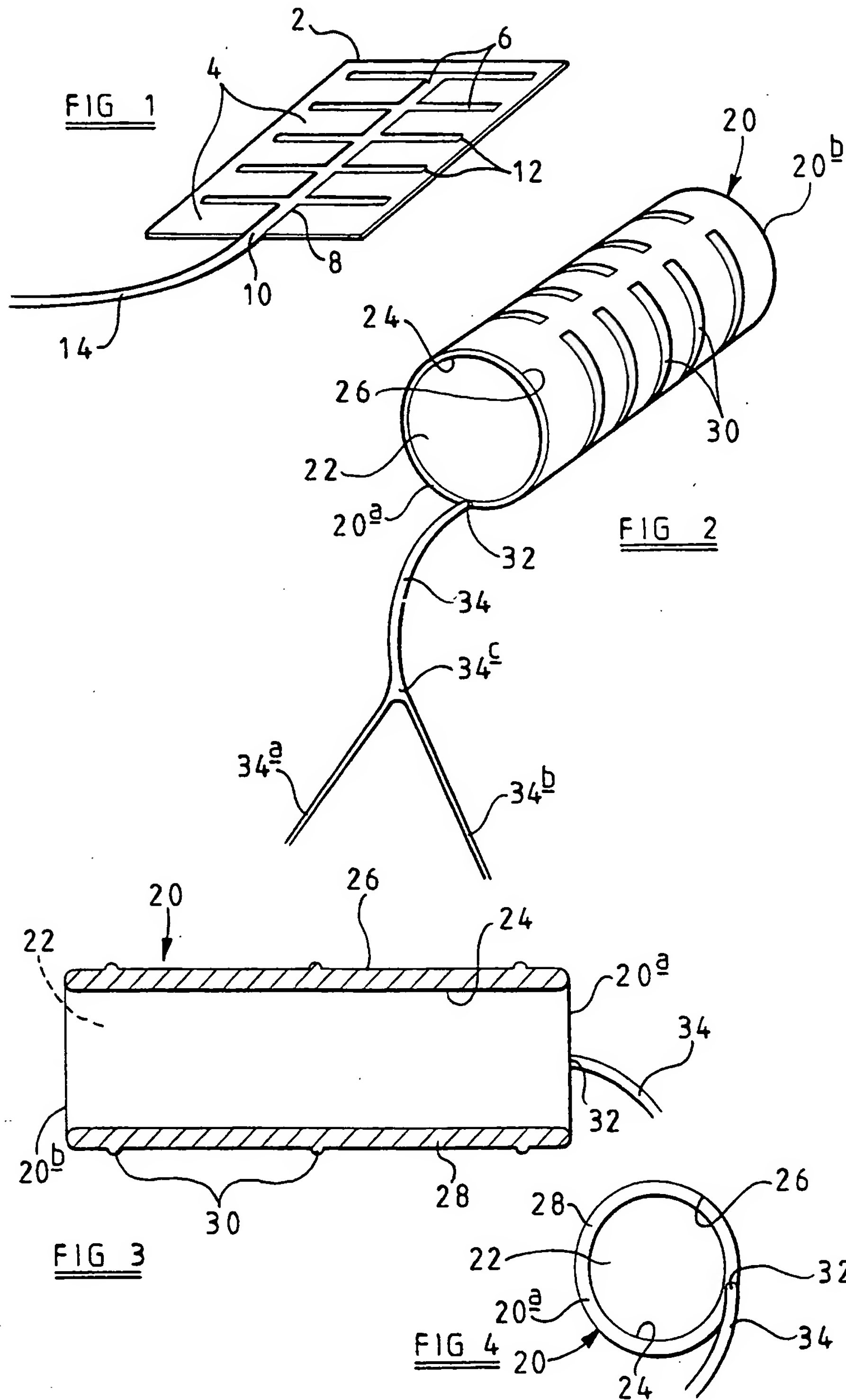
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by expansion of opposite ends of the body externally of respective opposite ends of the passage.

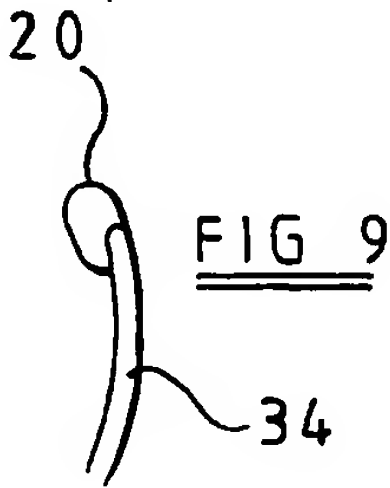
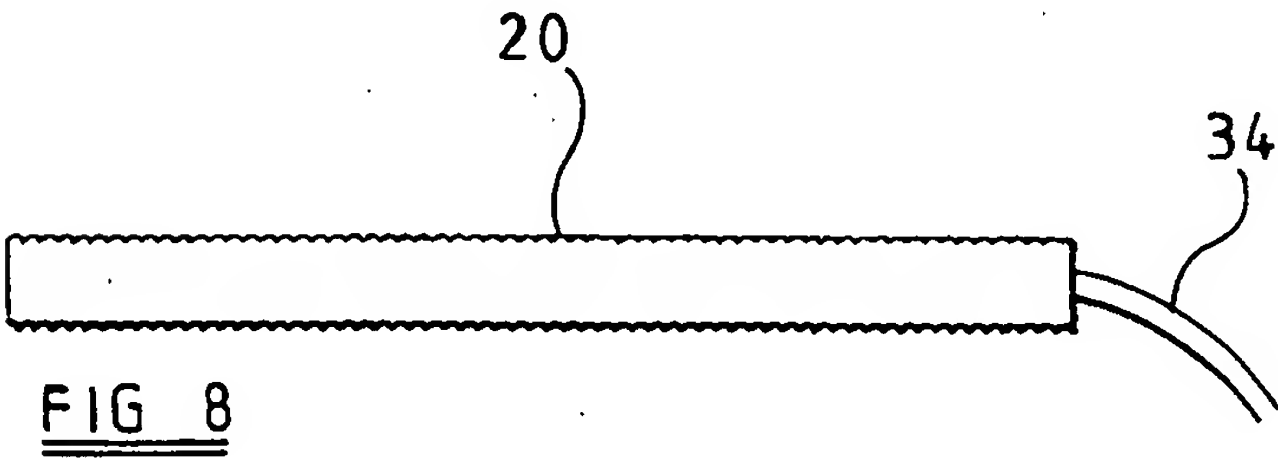
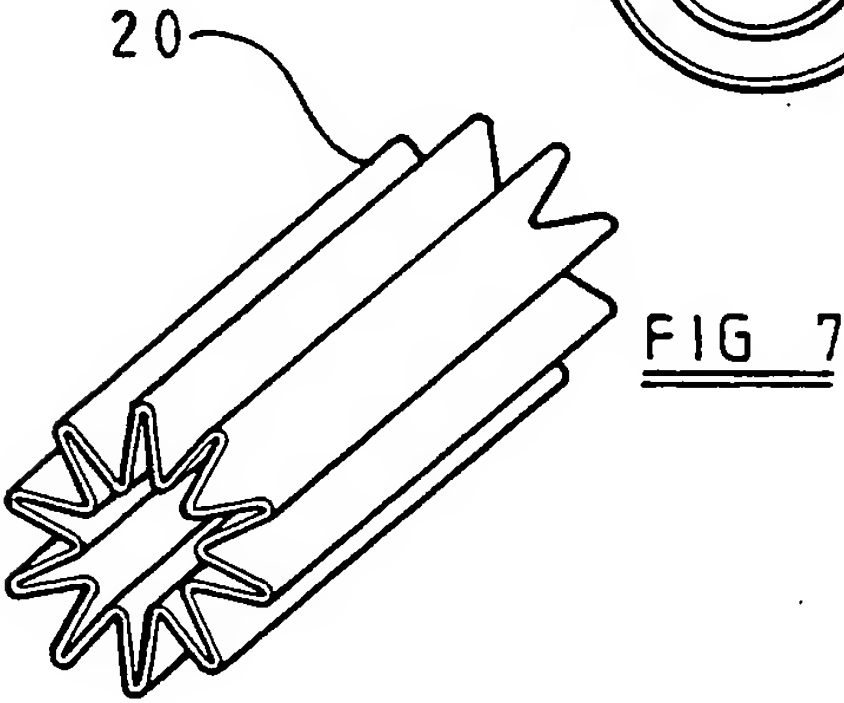
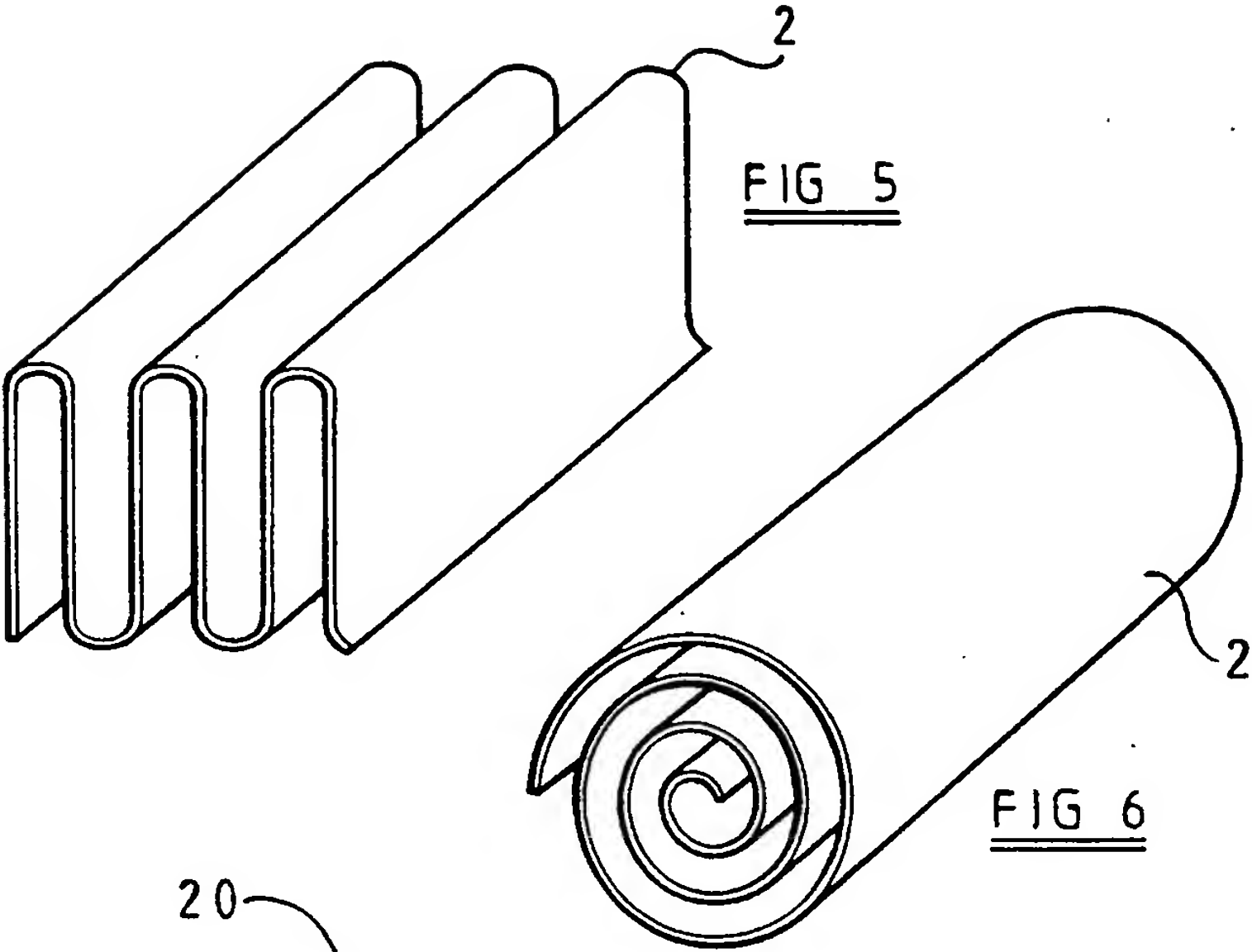
13. A method as claimed in any one of claims 9 to 12, wherein the rigidifying material is a chemically reactive liquid or other fluid which can be caused to solidify, gel or otherwise set or experience an increase in its viscosity when in the passage means in the body.

14. A method as claimed in any one of claims 9 to 13, wherein the rigidifying material itself is used to effect step (b) above by introducing it under pressure into the passage means in the body.

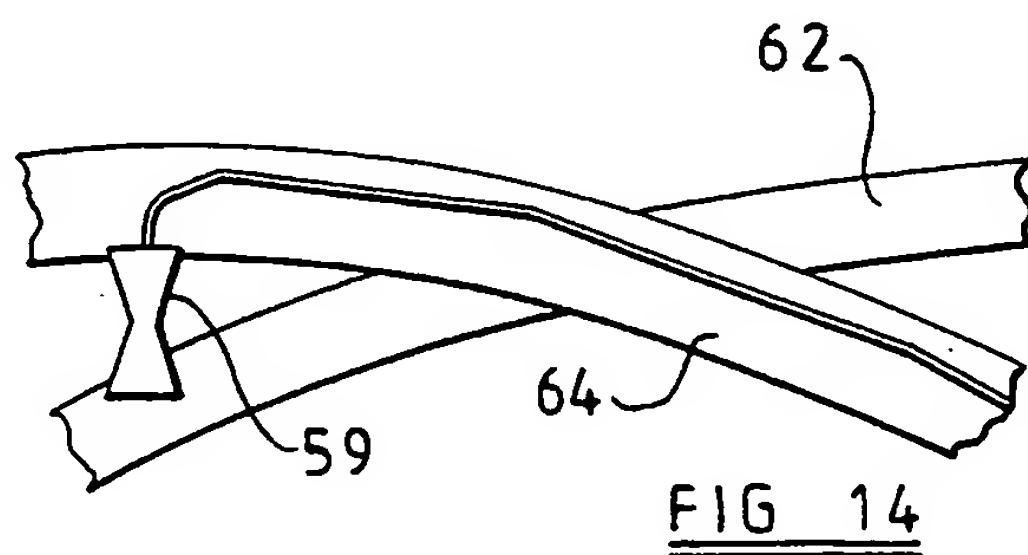
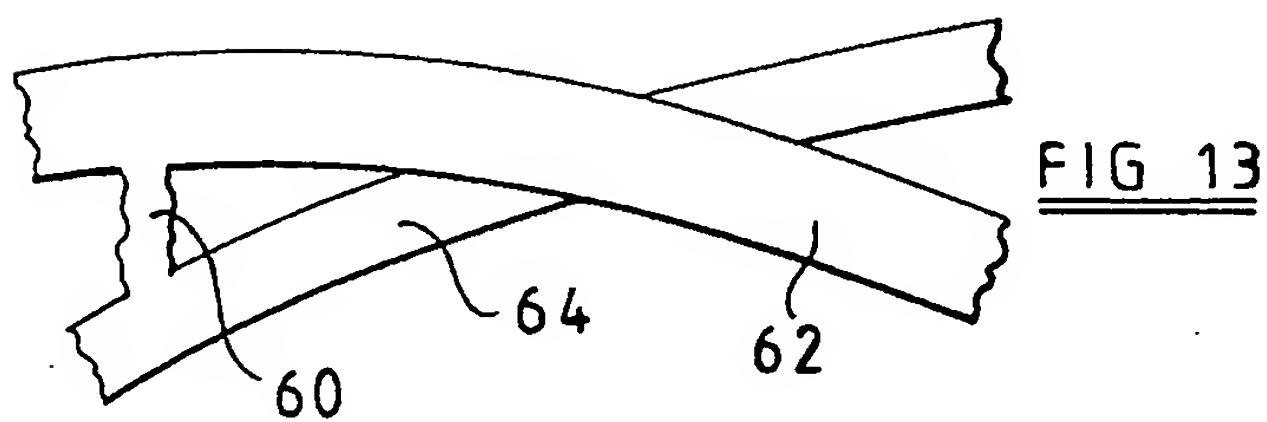
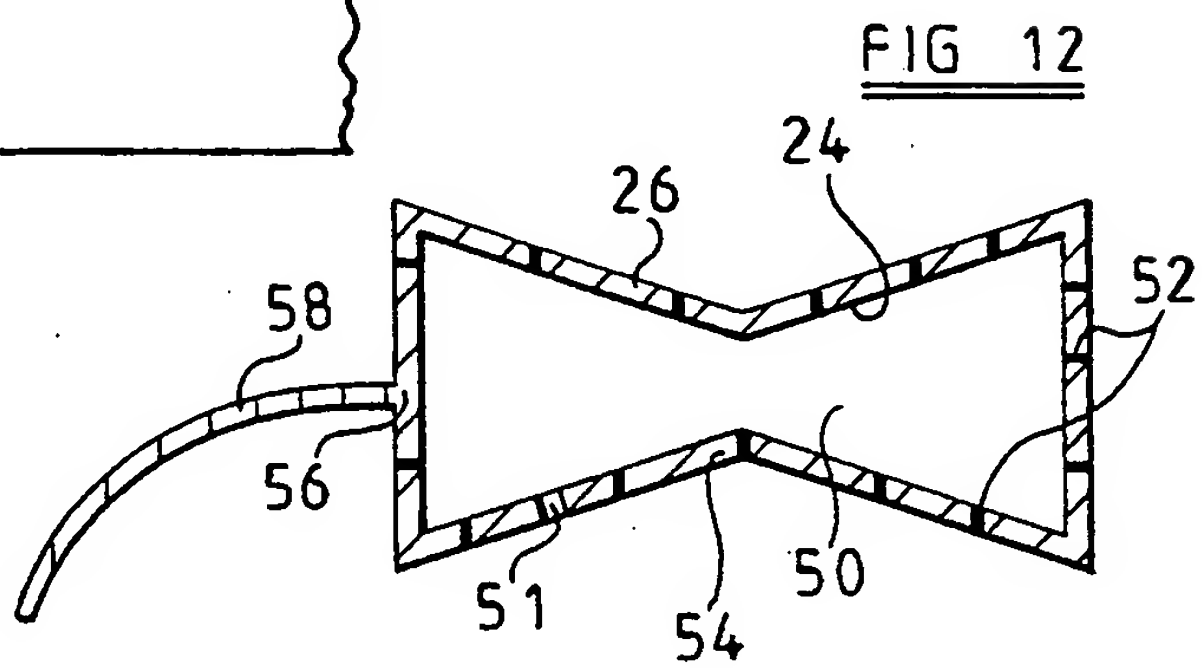
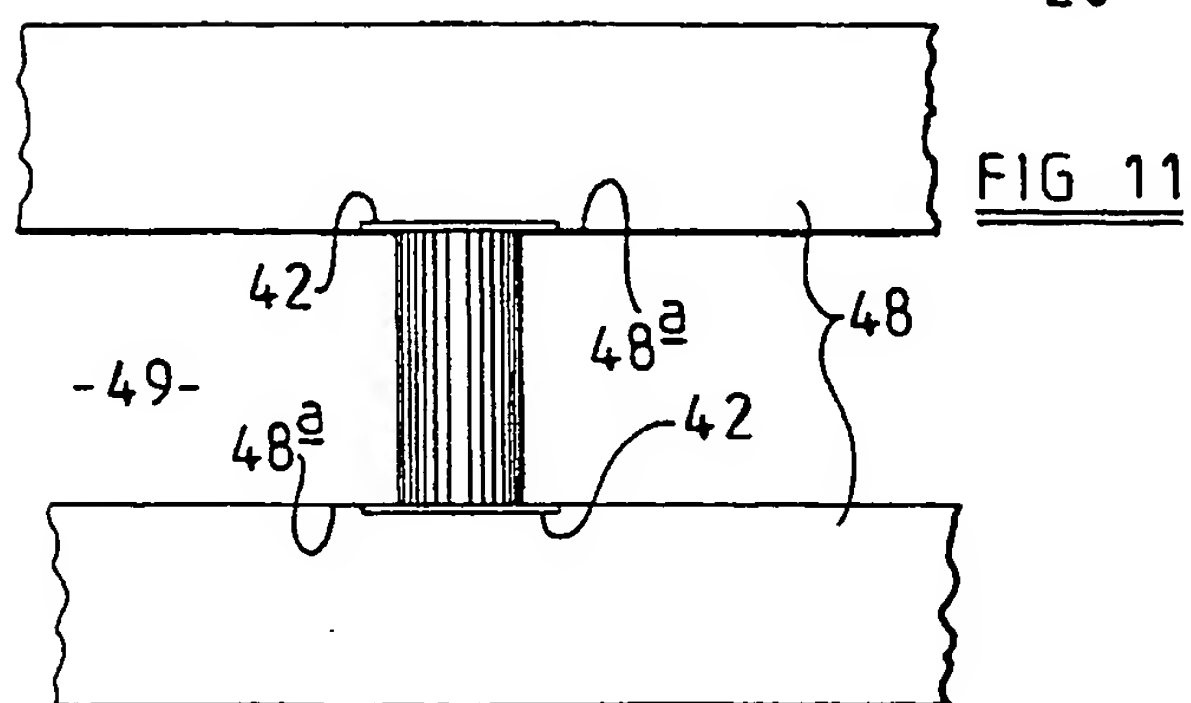
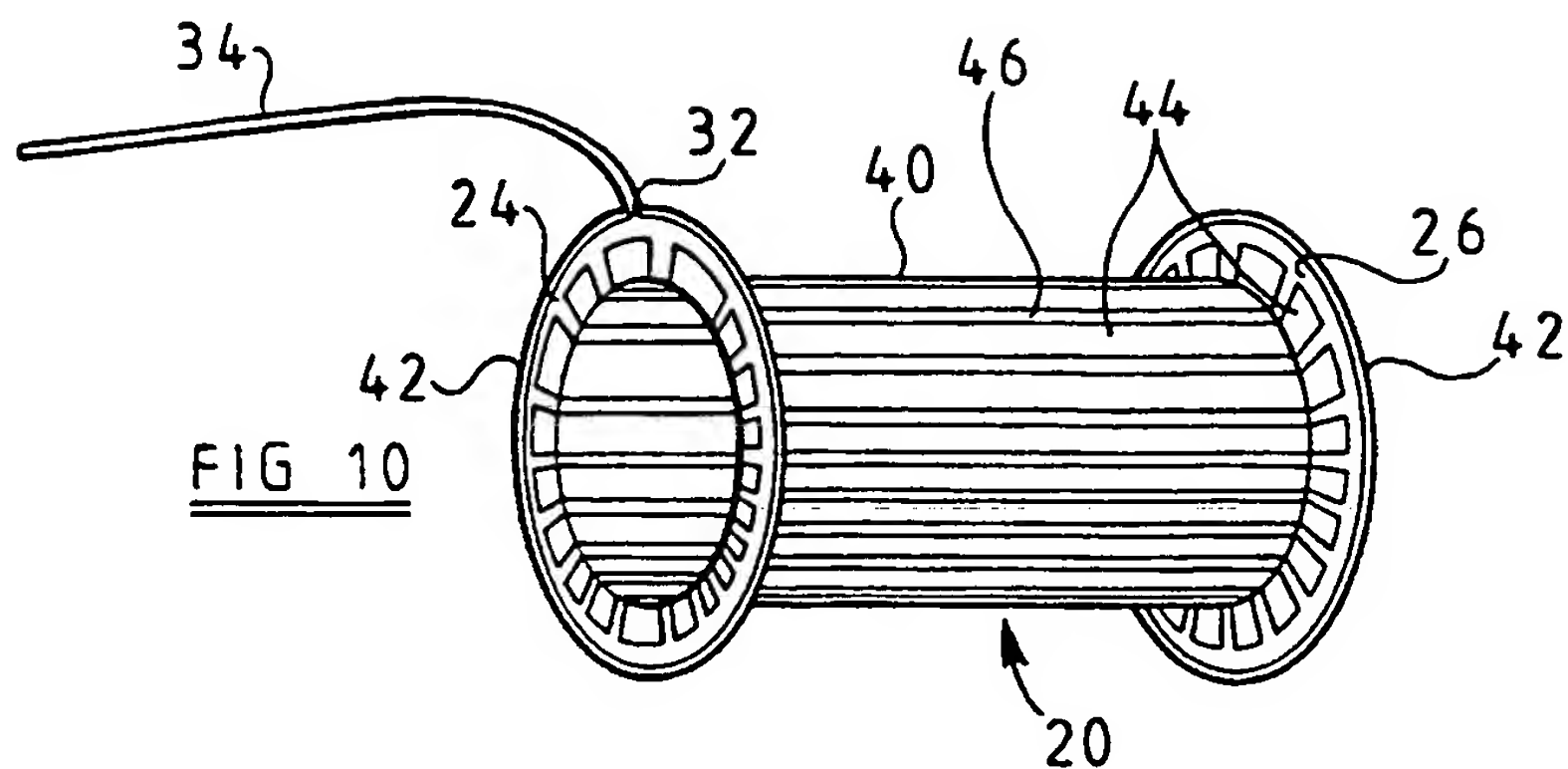
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INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 98/01850

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61F2/06 A61B17/12

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 19653 A (RHODES VALENTINE J) 5 June 1997 see figure 1 see figure 9 see page 8, paragraph 2 see page 13, line 20 - page 14, line 24 see page 16, line 15 - page 17, line 4 see claim 1 ---	1-8
X	US 5 156 620 A (PIGOTT JOHN P) 20 October 1992 see figure 1 see column 4, line 60 - column 5, line 13 see column 5, line 21 - line 43 see column 7, line 38 - line 50 see column 7, line 65 - column 8, line 8 see claim 1 --- -/--	1-8



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

8 October 1998

Date of mailing of the international search report

26/10/1998

Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

Int. .lonal Application No
PCT/GB 98/01850

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 441 516 A (PFIZER HOSPITAL PROD) 14 August 1991 see figure 1 see column 3, line 48 - line 56 see claim 3 ---	1-3
X	US 5 529 653 A (GLASTRA HENDRIK) 25 June 1996 see figure 1 see column 4, line 27 - line 48 ---	1
A	US 3 631 854 A (FRYER ROBERT HOWARD) 4 January 1972 see abstract see figures 4,8 see column 2, line 61 - column 3, line 38 ---	1-8
A	EP 0 617 930 A (INDUSTRIAL RES BV) 5 October 1994 see figures 1-3 see column 4, line 24 - line 49 see claim 1 -----	1

INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB 98/ 01850

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 9-14
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 98/01850

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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